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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,377	05/19/2005	Eric J. Sorscher	UAB-20402/22	2638

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EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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01/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,377

Applicant(s)

SORSCHER, ERIC J.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17,28,29 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17,28,29 and 36-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/14/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's election without traverse of the species corresponding to Formula VII in the reply filed on 5 November 2007 is acknowledged.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 28, line 15.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States,

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis et al. (A, newly cited).

Claim 1 is drawn to a kit for activating gene transfer, said kit comprising a gene transfer activating compound, packaged in a suitable container together with instructions for use to activate gene transfer. Claim 2 specifies within claim 1 that said gene transfer activating compound has a molecular weight of between 300 and 2000.

Hollis et al teaches, e.g., at the first full paragraph at column 12, a combination of DOTMA transfection reagent in a kit, said kit being taught as providing description of the

method of using the DOTMA. The variants of DOTMA all fall inherently within the molecular weight range as recited, i.e., approximately 610 or more.

Claims 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Felgner et al. (U, newly cited).

Claim 36 is drawn to a process for determining the efficacy of a putative gene transfer activating compound to activate gene transfer, comprising the steps of: administering a test compound to a first cell; contacting the first cell with a first amount of a recombinant vector; contacting a second cell with a second amount of the recombinant vector, the second amount of the recombinant vector substantially equal to the first amount; measuring a gene transfer indicator in the first cell to obtain a test measurement; measuring the gene transfer indicator in the second cell to obtain a control measurement; and comparing the test measurement and the control measurement to determine the efficacy of the putative gene transfer activating compound to activate gene transfer.

Felgner et al. teaches transfection, i.e., gene transfer, using DOTMA, e.g., as shown in the Abstract. Table 1 shows the testing of transfection with and without DOTMA.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole (3, cited on IDS).

Claim 1 is described above. Claim 4 specifies within claim 1 that said gene transfer compound is bouvardin.

Cole teaches, e.g., at the middle of column 1, bouvardin, as well as methods of using it therapeutically, e.g., at columns 3 and 4. Cole does not specifically teach the collection of bouvardin in a container with written instructions for its use, the actual content of the printed matter notwithstanding.

It would have been obvious to have packaged instructions for use of a pharmaceutical, as such is and was routinely (and necessarily) done in the art, and such a combination would be expected to function. The instructions for use are not functional in the invention, i.e., do not interact structurally with the container and/or bouvardin. As such, the actual content of the printed matter carries not patentable weight, and thus does not distinguish over the recited prior art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5-17, 28, 29 and 37-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 28 and 39, and therefore dependent claims 5-17, 37, 38 and 40-53, recite 6 molecular structures, with seven designations (Formulae I-VII). However, it is not clear which is Formula IV and which is Formula VI, as both appear to designate the same structure. It would appear that one of these two is redundant. As such, the claims are confusing and of unclear metes and bounds.

Each of claims 17, 29 and 53 recites a number of compounds with NSC accession numbers. However, there is no assurance that these numbers would remain assigned in the future in the same manner as the present or the time of filing. The exact structures intended are not disclosed in the specification, e.g., as drawn structures. As such, one of skill would not be certain in the future of the scope of the claims.

U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 37-53 provide for the use of the recited compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 37-53 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

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example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
19 January 2008


JAMES KETTER
PRIMARY EXAMINER